DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Radius Medical Technologies, Inc.
Maureen A. Finlayson
President
63 Great Road
Maynard, MA 01754

JUL 27 2015

Re: K011759
Trade/Device Name: Radius Medical Technologies Next Generation Guidewire
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY, GCA
Dated (Date on orig SE ltr): June 1, 2001
Received (Date on orig SE ltr): June 6, 2001

Dear Ms. Finlayson,

This letter corrects our substantially equivalent letter of August 23, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011759

Device Name: Radius Medical Technologies Next Generation Guidewire

Indications For Use:

The Next Generation Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile duct, cystic, pancreatic, and right and left hepatic ducts.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011759

AUG 2 3 2001

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510(k) Summary of Safety and Effectiveness

1. Sponsor Name

Radius Medical Technologies, Inc.
63 Great Road
Maynard, MA 01754
Telephone: 978 897 6469
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name: Next Generation Guidewire
Common/Usual Name: Guidewire
Classification Name: Endoscope and accessory

3. Identification of Predicate or Legally Marketed Device

The Next Generation Guidewire is substantially equivalent to the Microvasive Geenen Endotorque Guidewire (K942677)
Boston Scientific Microvasive Jagwire (510(k) number unknown)

4. Device Description

Radius Medical Technologies, Inc. has developed a line of Endoscopic guidewires ranging in sizes of 0.025" to 0.035" diameter and lengths of 260 cm to 450 cm (in standard and stiff body types). The wires will be offered with a 5 cm radiopaque distal tip (angled and straight). The wires are constructed of a solid nitinol core wire, which tapers at its distal end. A shrink jacket surrounds the core over the entire length except the distal most 5 cm. A radiopaque tube covers the distal 5 cm. Single striped bands of ink are placed circumferentially onto the jacket and spaced in 1 cm intervals beginning at the 6 cm location and continuing to the 40 cm location from the distal tip. Multiple ink bands are used to delineate the 10, 15, and 20 cm locations. A coating is applied over the tip portion of the guidewire.

5. Intended Use

The Next Generation Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile duct, cystic, pancreatic, and right and left hepatic ducts.

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6. Comparison of Technological Characteristics

The Next Generation Guidewire is substantially equivalent to the Boston Scientific Microvasive Jagwire and the Microvasive Geenen Endotorque Guidewire. The Radius Medical Next Generation Guidewire is substantially equivalent to the predicate devices listed, which provide the same or similar functions. The intended use and technological characteristics including, design, materials and method of operation support the concept of substantial equivalence.

7 Performance Testing

Testing on the Next Generation Guidewire includes distal tip tensile, torqueability, tip flexibility, coating adherence/integrity, and electrical resistance (in accordance with AAMI HF 18).